PATENT ABSTRACTS OF JAPAN

(11)Publication number : **02-059513**

(43)Date of publication of application : **28.02.1990**

(51)Int.Cl. **A61K 7/32**
A61K 7/16
A61K 9/70

(21)Application number : **63-209797**

(22)Date of filing : **24.08.1988**

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(54) ORAL CAVITY MUCOSA-ATTACHING TYPE HALITOSIS-PREVENTING AGENT

(57)Abstract:

PURPOSE: To provide the subject agent having remarkable odor-modifying, taste- modifying and deodorizing actions, preventing halitosis and having fast-acting and persisting properties without a feeling of physical disorder by comprising a water-soluble film which contains an active ingredient having a halitosis- preventing effect and is attached to an oral mucosa.

CONSTITUTION: The subject agent comprises a water-soluble film which contains an active ingredient having a halitosis-preventing effect and is attached to an oral mucosa. The active ingredient is selected from l-menthol, dl-camphor, peppermint oil, fennel fruit oil, gambir-catechu, etc., which exhibit mainly taste- modifying and odor-modifying, the content of the active ingredient being 0.1-5wt.%. A compound exhibiting the deodorizing effect includes flavonoid, cetylpyridinium chloride, etc., and the content of the compound is preferably 0.01-5wt.%. These active ingredients are preferably mixed and dispersed in a water-soluble film such as gelatin film and the thickness of the film is preferably 15-330μm.

LEGAL STATUS

[Date of request for examination]

[Date of sending the examiner's decision of rejection]

[Kind of final disposal of application other than the examiner's decision of rejection or application converted registration]

[Date of final disposal for application]

[Patent number]

[Date of registration]

[Number of appeal against examiner's decision of rejection]

[Date of requesting appeal against examiner's decision of rejection]

[Date of extinction of right]

XP-002129504

AN - 1990-110447 [25]
A - [001] 014 034 04- 06- 074 075 076 09- 101 135 137 230 231 24- 240 244 245 252 255 256 259 27& 435 477 52& 532 537 55& 56& 688 728
AP - JP19880209797 19880824; JP19880209797 19880824; [Based on J02059513]
CPY - KYUK-N
DC - A96 D21
FS - CPI
IC - A61K7/16 ; A61K7/32 ; A61K9/70
KS - 0044 0231 0409 0411 0906 1235 1985 1986 1989 2001 2007 2513 2575 2719 2761 3198 3201 3202
MC - A03-A00A A03-A04A1 A03-C01 A03-C02 A04-A03 A04-D05 A10-E09B2 A10-E21B A12-V04B D08-B08
PA - (KYUK-N) KYUKYU YAKUHIN KOGYO KK
PN - JP2059513 A 19900228 DW199015 000pp
- JP5041602B B 19930624 DW199328 A61K7/32 009pp
PR - JP19880209797 19880824
XA - C1990-048538
XIC - A61K-007/16 ; A61K-007/32 ; A61K-009/70
AB - J02059513 A new bad-breath-preventing agent to adhere to the buccal mucous membrane consists of a water-soluble film contg. a bad-breath-preventing ingredient and adhering to the mucous membrane.
- The content of the bad-breath-preventing agent(s) is pref. 0.1-5wt.%. The film is pref. based on one or a mixt. of polyvinyl pyrrolidone, gelatin, polyvinyl alcohol, sodium polyacrylate, carboyxmethyl cellulose, starch, xanthan gum, karaya gum, sodium alginate, methyl cellulose, carboxyvinyl polymer, agar, and hydroxypropyl cellulose. The film is opt. single-layer, double-layer, or laminate of three or more layers.
- USE - For providing a agent preventing bad breath effectively and durably (e.g., 2 hours or longer).
- (Dwg.0/6)
AW - GELATIN XANTHAN PVA STARCH GUM
AKW - GELATIN XANTHAN PVA STARCH GUM
IW - BAD BREATH PREVENT AGENT ADHERE BUCCAL MUCOUS MEMBRANE WATER SOLUBLE FILM POLYVINYL PYRROLIDONE
IKW - BAD BREATH PREVENT AGENT ADHERE BUCCAL MUCOUS MEMBRANE WATER SOLUBLE FILM POLYVINYL PYRROLIDONE
NC - 001
OPD - 1988-08-24
ORD - 1990-02-28
PAW - (KYUK-N) KYUKYU YAKUHIN KOGYO KK
TI - Bad-breath-preventing agent - is adhered to buccal mucous membrane using water soluble film e.g. polyvinyl pyrrolidone

English Translation of Japanese Patent No. 41602/1993

(Claims have already been translated beforehand)

DETAILED DESCRIPTION OF THE INVENTION

(Industrial application)

This invention concerns an oral cavity mucosa-adhering foul breath-preventing preparation, which is stuck directly in an oral cavity and hence eliminates foul smell in breath.

(Customary technology)

So far foul breath-preventing preparations are administered in form of liquid, paste, spray, lozenge and pill. Where and when a liquid or paste preparation can be used is limited, as it is sometimes troublesome to deal with the liquid or paste after they are used to mouthwash. A preparation in form of spray, lozenge or pill has advantages of being easily carried and applied, but the effect of spray does not last long. Furthermore a lozenge and a pill have both the disadvantage of impeding speech being a foreign body in the mouth and they can be easily chewed down and swallowed, giving the effect only for a short time. Considering the points mentioned above a lasting foul breath-preventing effect can not be expected with currently available preparations.

(Task to be dealt with by this invention)

This invention solves the problems mentioned above and it's aim is to provide a method of preventing foul smell arising in an oral cavity for a long period of time. Further the object of this invention is to provide an oral cavity mucosa-adhering foul breath-preventing preparation, whose water- soluble polymer substance contains an active ingredient preventing foul breath.

(Method to solve the task)

Thereupon, these inventors had carefully studied and looked for a form suitable for the purpose and came to the conclusion that a preparation in form of film satisfies the necessary conditions, staying adhered to oral cavity mucosa and not coming off easily, having a form and a character, which do not create a feeling of having a foreign body in the sensitive oral cavity and releasing active ingredients slowly over a long period.

It is also necessary for the active ingredient preventing foul breath, which is contained in the film preparation, to have characters of correcting taste and odor, and eliminating foul smell.

In this invention the water-soluble polymer is made to retain the active ingredient preventing foul breath and to form a monolayer or a multilayer film-preparation, which enables prevention of foul breath continuously over a period of time.

Active ingredients comprise of two types of components (a) and (b) , and for the component (a) the following can be mentioned; 1-menthol, dl-camphor, peppermint oil, fennel oil, gambir, licorice, chlorophyllin derivatives, cinnamon, pepper, amomum seed, ginger, clove, red pepper, dl-menthol, hyakusou" , saussrea root, bitter cardamon, Borneo camphor, nutmeg, clove oil, cinnamon

oil, saffron, rose oil, green powdered tea. At least one of the components (a) can be contained. These components show the effect of correcting taste and odor, and the suitable content of each component is 0.1 to 5% in weight ratio. As the other effective component (b) the following can be mentioned ; flavonoids, cetyl pyridinium chloride, chlorhexidine chloride, decalinium chloride and chlorhexidine gluconate, and at least one of these component (b) can be contained. These components show the effect of eliminating smell and the suitable content of each component is 0.01 to 5% in weight ratio. The lowest limit in content is 0.1% for component (a) and 0.01% for component (b) and when the content is below the limit, the concentration is too low to give the expected foul breath preventing effect. On the other hand, an improvement in preventive effect can not be expected, even when the content is raised over 5%. Furthermore, the components, whose main effect is to correct taste and odor, and components, whose main effect is to eliminate smell, can be used together as long as there is no pharmacological problem.

It is absolutely necessary for the above mentioned active ingredients with foul breath preventing action to be uniformly mixed and dispersed in the water-soluble film, and in order to attain the purpose of this invention it is not satisfactory just to apply them on the film or simply bury them in the film.

The above mentioned water-soluble film refers to the kind, which is dissolvable mainly in an oral cavity and in the stomach. Possible candidates of polymer substances include among others polyvinylpyrrolidone, gelatin, polyvinyl alcohol, poly(sodium acrylate), carboxymethyl cellulose, starch, xanthan gum, karaya gum, sodium alginate, methyl cellulose, carboxyvinylpolymers, agar, and hydroxypropyl cellulose and the water-soluble film is constructed mainly out of at least one of these polymers. The aforesaid hydroxypropyl cellulose is used most advantageously, when high viscosity hydroxypropyl cellulose (abbreviated as 'HPC-H' hereafter) and low viscosity hydroxypropyl cellulose (abbreviated as 'HPC-L') are according to their special character appropriately employed.

It necessarily follows that the water-soluble film should be edible and it is desirable that the finished preparation is not so thick. In practice factors such as the dissolving rate of the water-soluble film, sustainment of the medicinal effect, uncomfortableness due to foreign body etc. are taken into account to decide the thickness of the film. When the film is too thin, although it depends on the kind of film, it dissolves too fast and therefore thickness greater than 15 μm is desirable. On the other hand the film should not be thicker than 400 μm, preferably less than 330 μm, because when the film is thicker, the majority, though there are individual differences, unpleasantly notices the foreign body.

In order to have the active ingredients contained uniformly in the thin film and to control the thickness of the final preparation, it is of importance to choose appropriate solvents, in which the active ingredients and the substances to form a thin film are dissolved or dispersed.

Since these solvents will be taken into the body through the usage of the current preparation in an oral cavity, they should have, of course, no toxic effect towards humans at all. The solvents must also have a relatively small specific heat, as the solvent is distilled off, after film material is cast-stretched.

Moreover, the smallest possible amount of solvent should be used, when the removal of solvent is concerned, to dissolve the necessary amount of ingredients and accordingly an appropriate solvent must be chosen.

Considering the above mentioned points, the solvents in this invention are chosen and limited to water, ethanol and methylene chloride, and on this basis the other components to form an adhesive plaster are selected, which allow to obtain an effective preparation, that has a thickness of 15 to 330 μm and shows a lasting efficacy in giving satisfactory effect.

When preparing the preparation of this invention it is beneficial to apply Macrogol 400, glycerin etc. as a plasticizer for the water-soluble film. Desirable solvents for preparing a water-soluble film are water, ethanol and methylene chloride.

Further the water-soluble films are ,depending on the rate of dissolution, divided into two groups, slow dissolving and fast dissolving ones. Each type of the films can either be used alone or they can be used in appropriate combinations in order to form a foul breath-preventing preparation of the current invention.

(Effect of the invention)

The foul-breath preventing preparation of this invention, constructed as described above, shows a reliable effect, since while the film dissolves, the effective components, which are contained in the water-soluble film, are released from the adhered part and diffuse into the whole oral cavity.

Especially the water-soluble film of this invention adheres as a whole to the oral cavity mucosa, adjusting to the form of the application area, it's effect is more quickly spread over the whole oral cavity than from preparations, where effective components are either just buried in the film or spread on the film. These structural characteristic together with accurate medicinal effect works synergistically to eliminate foul breath through masking by odor correcting activity and through the foul smell-extinguishing activity. Moreover when the slow dissolving film is combined with the fast dissolving one to give a multilayer film in this invention, the film dissolving period is prolonged and the foul breath-preventing effect lasts longer.

In order to show the foul breath preventing efficacy and ist lasting effect of this invention, analyses with gas chromatography were performed. Methylmercaptan was chosen as a possible volatile stinking substance, causing foul breath. An oral cavity was cleansed with a mouthwash, gargled with an artificial foul breath-causing solution, 10ml for 1 minute, and directly after spitting out the solution each foul breath-preventing preparation was applied. The head space gas of breath was analyzed by gas chromatography after certain intervals. The results are shown in the table below and in Diagram 6.

Remaining % Methymercaptan vs. Time

Time(min)	1	3	5	10	20	30	60	120
This invention	77	62	50	42	40	40	40	40
Lozenge	95	80	755	70	60	70	95	
Liquid	50	50	60	65	80	95		
Paste	60	57	65	85	95			
Pill	75	70	65	60	60	75	95	

The above results show that all preparations except the current invention (Example 33) lose their efficacy after 20 minutes or so and artificial foul breath reappears. The preparation of this invention, however, managed to eliminate the foul smell from 60% of methylmercaptan after 20 minutes and sustained this condition for 2 hours.

As seen above the preparation of this invention having a construction, in which active ingredients are contained in a water-soluble film, manages to prevent foul breath through the significant effect of correcting taste and smell and eliminating odor and showed to be very effective in practical use, as it gives no foreign body feeling due to being a thin film adhering to an oral cavity mucosa and it showed an immediate and lasting effect.

(Examples)

Examples for this invention are shown below but this invention is not limited to what is shown in the examples.

Diagrams show examples of a water-soluble film, consisting of a monolayer of fast dissolving film 1 (Diagram 1), one consisting of a monolayer of fast dissolving film 2 (Diagram 2), one consisting of a doublelayer film out of the aforesaid films 1 and 2 (Diagram 3) and one consisting of three-layer film, where a slow dissolving film 2 is sandwiched between two layers of fast dissolving films (Diagram 4). Both films 1 and 2 adhere to an oral cavity mucosa, to which they come in close contact, but the other side of the film looses its adhesive quality due to constantly present saliva (Diagram 5). The fast dissolving and slow dissolving films are combined to give immediate and long lasting effect, respectively. Both kinds of film are made of material dissolving in the oral cavity , which consists of at least one of polyvinylpyrrolidone, gelatin, polyvinyl alcohol, poly(sodium acrylate), carboxymethyl cellulose, starch, xantan gum, karaya gum, sodium alginate, methyl cellulose, carboxyvinyl polymers, agar, hydroxypropyl cellulose etc. and the rate of dissolving is adjusted by altering the ratio of each component. Further the active ingredients are contained throughout the whole film.

<Example 1>

A fast dissolving film (adhesive layer): Active ingredients of 2.5 parts by weight (abbreviated as w.p. hereafter) 1-menthol, 2.0 w.p. peppermint oil and 1.0 w.p. fennel oil (as shown at Example 1 in Table 1) together with 10 w.p. HPC-H, 30 w.p. HPC-L, 44.5 w.p. polyvinylpyrrolidone (PVP), and 10 w.p. Macrogol 400 as a plasticizer are dissolved in 1000 w.p. ethanol, cast –

stretched, and dried to form an oral cavity mucosa-adhering foul breath-preventing preparation, consisting of a 122 μm thick monolayer film.

<Examples 2 to 8 >

Active ingredients, components for forming films and their ratios are altered as shown in Examples 2 to 8 in Table 1, and are processed as in Example 1 to form oral cavity mucosa-adhering foul breath-preventing preparations, which are7 different types of monolayer films, whose thicknesses are given at the bottom of Table 1. However, the solvent used is altered to 1000 w.p. water in Example 6 and 1000 w.p. methylene chloride in Example 7, respectively.

The above mentioned foul breath-preventing preparations made of fast dissolving films (Example 1 to 8) were applied to an oral cavity mucosa and tested for practical use. It was found thatall preparations of this group adhered to an oral cavity mucosa without causing foreign body feeling and stayed adhered, showing the foul breath protecting effect till they had dissolved completely after 30 to 40 minutes.

<Example 9 >

A slow dissolving film (adhesive layer); Active ingredients of 2.0 w.p. 1-menthol, 2.0 w.p. peppermint oil and 0.5 w.p. fennel oil (as shown at Example 9 in Table 2) together with 40 w.p. HPC-H 40, 20 w.p. HPC-L20, and 35.5 w.p. PVP are dissolved in 1000 w.p. ethanol, cast-stretched, and dried to form an oral cavity mucosa-adhering foul breath-preventing prepation, consisting of a 25.4 μm thick monolayer film.

<Examples 10 to 16 >

Active ingredients, film components and their ratios are varied as indicated in Examples 10 to 16 in Table 2, and processed as in Example 9 to form oral cavity mucosa-adhering foul breath-preventing preparations, consisting of 7 different types of monolayer films. Their thicknesses are shown at the bottom of Table 2.

The foul breath-preventing preparations out of slow dissolving films above (Examples 9 to 16) were applied to an oral cavity mucosa and tested for practical use. It was found that, all preparations of this group also adhered to an oral cavity mucosa without causing foreign body feeling and stayed adhered, showing the foul breath-protecting effect, till they had dissolved completely after 40 to 60 minutes.

<Example 17 to 24 >

On a 122 μm thick fast dissolving film (adhesive layer), prepared as in the Example 1, the dissolved mixture, as indicated in Example 9, was cast-stretched and after drying a 25 μm thick slow dissolving film layer was formed. The resulting double-layer oral cavity mucosa-adhering foul breath-preventing preparation consists of a slow and a fast dissolving film and is 147 μm thick (Table 3).

Oral cavity mucosa-adhering foul breath-preventing preparations, consisting of double layer films, are prepared in the same manner as described above, in various combinations, starting with a combination of a fast dissolving film of Example 2 in Table 1 and a slow dissolving film of Example 10 in Table 2, giving a 177 μm thick double layer film, to a combination of films of Example 8 and Example 16, as shown in the upper half of Table 3.

The combinations described above (Examples 17 to 24) and the thicknesses of resulting preparations are given in the upper half of Table 3. The double layer foul breath-preventing preparations were applied and tested for practical use. The time, in which the preparations show foul breath preventing effect, was prolonged in general and moreover it showed the effective time to be roughly proportional to the thickness of the preparation. The preparation of Example 20, however, had a thickness of 396 μm, which exceeds our standard thickness of 330 μm, and was found by some people to be uncomfortable, causing foreign body feeling.

<Examples 25 to 32>

The fast dissolving film of Example 1 was cast-stretched on both sides of the slow dissolving film of Example 9 to give a three layer oral cavity mucosa-adhering foul breath-preventing preparation (Example 25) and the thickness was a cumulative thickness of three layers, 269 μm.

Other three layer foul breath-preventing preparations were made, using various combinations of components as shown in the lower half of Table 3. The effective time periods of this group of foul breath-preventing preparations were significantly longer, compared to the periods of two former groups of preparations. In some cases (Examples 27,28) effective time exceeded 1 hour, but since the feeling of foreign body became apparent, they were considered to be of no practical use.

<Examples 33 to37 >

In this group of Examples flavonoid and other four odor eliminating agents are employed as active ingredients and the water soluble films employed here are the fast dissolving ones, as in Examples 1 to 8, (except in Example 33, where a slow dissolving film was used). However, of course, it is possible to combine these films with slow dissolving films (in Example 33, with a fast dissolving film).

In Example 33, 1.0 w.p. flavonoid as a active ingredient together with 40 w.p. HPC-H, 20 w.p. HPC-L and 39 w.p. PVP, was dissolved in 1000 w.p. ethanol and the resulting solution was cast-stretched and dried to form an oral cavity mucosa-adhering foul breath-preventing preparation, consisting of a 200 μm thick monolayer film.

In Example 34 cetyl pyridinium chloride, in Example 35 chlorhexidine chloride, in Example 36 decalinium chloride, and in Example 37 chlorhexidine gluconate are used as active ingredients, respectively, and otherwise foul breath-preventing preparations were formed in the same manner as described above.

<Example 38 to 42>

Examples in which active ingredients for correcting taste and smell such as 1-menthol etc. are used together with active ingredients for eliminating odor such as flavonids etc. and their combinations are shown in Table 5. Here also the fast dissolving films were employed like in Examples 34 to 37 (except in Example 38, where a slow dissolving film was used). However, here also the films can be employed in combination with slow dissolving films (in Example 38, combination with a fast dissolving film).

In Example 38 flavonoids, 1-menthol and peppermint oil are used as active ingredients and in Examples 39 to 42 the active ingredients as indicated in table 5 are used to form the foul breath-preventing preparations of this invention in the same manner as described above.

In the same manner in which the films of Examples 1 to 8 and the films of Examples 9 to 16 were combined to form double layer films, the films of Examples 9 to 16 were combined with the films of Example 34 to 37 and with the films of Example of 39-42. The films of Examples 1 to 8 were also combined with the films of 33 and 38. Most of the preparation from above mentioned combinations were studied and found that they generally do not give favorable results.

(Brief explanation of diagrams)

All diagrams concern the oral cavity mucosa-adhering foul breath-preventing preparation of this invention and diagram 1 to 5 are magnified sectional schemes, showing sectional structure and the diagram 6 is a graph, showing the efficacy of this invention in preventing foul breath.

TABLE 1

Fast dissolving Film

Example Ingredient	1	2	3	4	5	6	7	8
	1-menthol 2.5		1-menthol 1.0		1-menthol 2.0		1-menthol 2.0	
	Peppermint oil 2.0	d,l-Camphor 1.0	Gambir 0.5	Clove 1.0	„Hyakusou" 0.5	Borneo Camphor 0.5	Pepper 1.0	Powdered green tea 1.0
	Fennel oil 1.0	d,l-Menthol 0.5	Licorice 1.5	Cinnamon oil 1.5	Saussurea root 0.5	Red pepper 0.5	Ginger 1.0	Chlorophylin derivatives 2.5
		Clove oil 0.5	Cinnamon 0.5	Bitter cardammon 1.0	Nutmeg 0.5	Amomum seed 1.0	Rose oil 0.5	Saffron 0.5
HPC-H	10	10			30	10	10	10
HPC-L	30		10	10	10	30	30	10
PVP	44.5	34.0	36.5	34.5	46.5	43.0	45	45.0
Macrogol 400	10	10	10	10	10	10	10	10
Na -alginate		40						
MC*			40					
Agar				40				
Ethanol	1000	1000	1000	1000	1000			1000
Water						1000		
Methylene chloride							1000	
Thickness of preparation	122 µm	121 µm	210 µm	328 µm	89 µm	117 µm	109 µm	91 µm

* Methyl cellulose ? (translators comment)

TABLE 2
Slow dissolving Film

Example Ingredient	9	10	11	12	13	14	15	16
	1-menthol 2.0		1-menthol 1.5		1-menthol 0.5		1-menthol 2.5	
	Peppermint oil 2.0	d,l-Camphor 0.5	Gambir 0.5	Clove 0.5	„Hyakusou“ 0.5	Borneo Camphor 0.5	Pepper 0.5	Powdered green tea 0.5
	Fennel oil 0.5	d,l-Menthol 0.5	Licorice 1.0	Cinnamon oil 0.5	Saussurea root 1.0	Red pepper 0.5	Ginger 1.0	Chlorophylin derivatives 0.5
		Clove oil 0.5	Cinnamon 0.5	Bitter cardammon 1.0	Nutmeg 0.5	Amomum seed 0.5	Rose oil 1.0	Saffron 0.5
HPC-H	40	40	40	40	40	40	40	40
HPC-L	20							
PVP	35.5	25.5	26.5	25.0	37.5	34.5	25.0	35.0
Gelatine			40					
Polyvinyl alcohol					20			
Polyacrylate				30				
CMC*					20			
Starch		30						
Xanthan gum							30	
Karaya gum								20
Ethanol	1000	1000	1000	1000	1000	1000	1000	1000
Thickness of preparation	25.4 µm	56.3 µm	58.2 µm	68.7 µm	81.4 µm	86.5 µm	97.7 µm	104.6 µm

* Carboxymethyl cellulose ? (translators comment)

TABLE 3

Example	Components	Thickness of preparation (µm)
17	Example 1+9	147
18	Example 2+10	177
19	Example 3+11	268
20	Example 4+12	396
21	Example 5+13	170
22	Example 6+14	203
23	Example 7+15	206
24	Example 8+16	195
25	Example 1+9+1	269
26	Example 2+10+2	298
27	Example 3+11+3	478
28	Example 4+12+4	725
29	Example 5+13+5	259
30	Example 6+14+6	320
31	Example 7+15+7	315
32	Example 8+16+8	286

TABLE 4
Fast dissolving Film

Example Ingredients	33	34	35	36	37
	Flavonoids 1.0	Cetyl pyridinium chloride 0.03	Chlorhexidine hydrochloride 0.01	Decalinium chloride 0.02	Chlorhexidine gluconate 0.03
HPC-H	40	10	10	10	10
HPC-L	20	30	30	30	30
PVP	39	59.97	59.99	59.98	59.97
Macrogol 400		10	10	10	10
Ethanol	1000	1000	1000	1000	1000
Thickness of preparation	200 μm	200 μm	200 μm	200 μm	200 μm

(Example 33 is a slow dissolving film)

TABLE 5
Fast dissolving Film

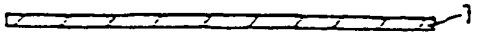
Example Ingredients	38	39	40	41	42
	Flavonoids 1.0	Cetyl pyridinium chloride 0.03	Chlorhexidine hydrochloride 0.01	Decalinium chloride 0.02	Chlorhexidine gluconate 0.03
	1-Menthol 2.5	Powdered green tea 1.0	Rose oil 0.5	d,l-Camphor 1.0	Cinammon 0.5
	Peppermint oil 2.0	Chlorophyllin derivatives 2.5			
HPC-H	40	10	10	10	10
HPC-L	20	30	30	30	30
PVP	37.0	56.47	59.49	58.98	59.47
Ethanol	1000	1000	1000	1000	1000
Thickness of preparation	200 μm	200 μm	200 μm	200 μm	200 μm

(Example 38 is a slow dissolving film)

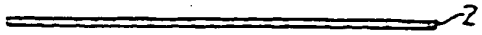
成分／実施例	38	39	40	41	42
	ハッカ油 2.0	クロロ 2.5			
HPC-H	40	10	10	10	10
HPC-L	20	30	30	30	30
PVP	37.0	56.47	59.49	58.98	59.47
エタノール	1000	1000	1000	1000	1000
剥厚 (μm)	200	200	200	200	200

(但し実施例38は速溶解性フィルム)

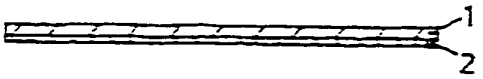
第1図　Diagram 1



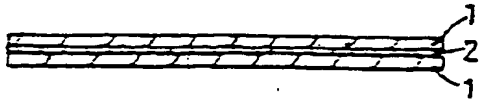
第2図　Diagram 2



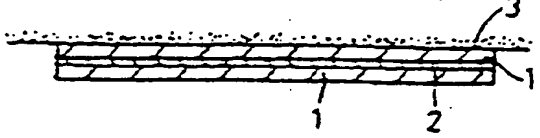
第3図　Diagram 3



第4図　Diagram 4



第5図　Diagram 5



第6図

● 本発明品 – Preparation of this invention
○ トローチ剤 – Lozenge
△ 液 剤 – Liquid
● 練 薬 – paste
▲ 丸 剤 – Pill